

Food and Drug Administration, HHS

§ 520.88c

and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(1) *Conditions of use*—(i) *Dogs*—(A) *Amount*. 5 milligrams per pound of body weight twice daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis*; genitourinary tract (cystitis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal tract (bacterial gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; and soft tissues (abscesses, lacerations, and wounds) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Cats*—(A) *Amount*. 50 milligrams (5 to 10 milligrams per pound) once daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis*; genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium*

spp.; gastrointestinal tract due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

(c) *Sponsors*. See Nos. 000856 and 051311 in § 510.600(c) of this chapter.

(1) *Conditions of use*. *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight twice daily.

(ii) *Indications for use*. Treatment of bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *E. coli*, and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis* and *Staphylococcus* spp.

(iii) *Limitations*. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 13302, Mar. 20, 1997; 67 FR 67521, Nov. 6, 2002; 68 FR 54658, Sept. 18, 2003; 68 FR 55824, Sept. 29, 2003]

§ 520.88c Amoxicillin trihydrate oral suspension.

(a) *Specifications*. Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*. *Swine*(1) *Amount*. 40 milligrams orally, twice a day using a dosing pump.

(2) *Indications for use*. Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by *Escherichia coli* susceptible to amoxicillin.

(3) *Limitations*. Treat animals for 48 hours after all symptoms have subsided